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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,788	02/25/2004	Jose L. Navia	CCF-6448NP	3699

7590 01/13/2005

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,788	NAVIA ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/25/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 12, 18, & 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected as follows: (i) with respect to claims 12 & 21, they both depend from claim 1 and recite the same limitations directed to a sheath, therefore one should be cancelled since it is not further limiting; (ii) with respect to claims 8 & 18, they both depend from claim 1 and recite the same limitations, therefore one should be cancelled since it is not further limiting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-15, & 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Navia et al. (US 6,340,356). Navia discloses a system having an intraluminal catheter having a main body with a proximal end and a distal end, an expandable stent disposed on its distal end, an occluding means that is also on the distal end and may be within the stent, and a proximal end that has a connector that

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may be connected to an external artery via external tubing. The occluding means may be an umbrella-shaped membrane or a balloon. The membrane may have at least one to multiple openings to allow blood flow therethrough, and said membrane occluder has a span of a distance between the interior wall of the vessel the device resides in and the outer surface of the cannula. The cannula may have multiple lumens and a plurality of openings in fluid communication to the lumens. The system further includes a sheath. Navia et al. discloses a method for use of said system for retroperfusing a coronary vein, which reads on the method as claimed by applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 5 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al. ('356) in view of Ciamacco, Jr. (US 5,938,582). Navia et al. substantially discloses the invention as claimed, however, does not teach that the occluding balloon has a plurality of lobes defining radial gaps between the lobes. Ciamacco, Jr. discloses a catheter having multiple lobes with spaces or valleys between each lobe that will allow for blood flow. See figures. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the balloon of Navia et al. to be a balloon having multiple lobes as taught by Ciamacco, Jr. to prevent complete blockage of fluid flow around the occluder.

Claims 6-9, 17-19, & 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al. ('356) in view of Nelson et al. (US 5,824,071). Navia et al. substantially discloses the invention as claimed, however, does not teach that the proximal end of the cannula has a graft or catheter attached thereto for suturing to an artery. Nelson et al. discloses a method and apparatus for providing retroperfusion to the myocardial tissue. The apparatus includes a graft or catheter tubing means connected to a first conduit for connection to an artery to provide oxygenated blood to the first conduit, which will be placed in a coronary vessel. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the catheter system of Navia et al. such that a graft or catheter is connected to the proximal end of the cannula, which is to be inserted in a coronary vessel, to provide oxygenated blood to the first conduit and thereby the surrounding tissue.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shmulewitz (2001/0027287) discloses an analogous catheter system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 8th, 2005


PATRICIA BIANCO
PRIMARY EXAMINER Patricia M Bianco
Primary Examiner
Art Unit 3762